Paper No. 30

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MATTHEW B. WHEELER



Appeal No. 2001-0695
Application No. 08/410,539

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-6, 9-12, and 15-20, all of the claims remaining. Claims 1 and 15 are representative and read as follows:

1. A method for making a chimeric ungulate comprising:

(a) introducing a cultured ungulate embryonic stem cell that has a first genetic complement into a recipient embryo of the same species as the embryonic stem cell, said recipient having a second genetic complement, to form a chimeric ungulate embryo; and

(b) placing the chimeric ungulate embryo in an environment suitable for the completion of development to form a chimeric ungulate.

15. A method of isolating and purifying an embryonic stem cell culture, said method comprising:

(a) preparing a first culture by culturing dissociated cells from an ungulate embryo in conditioned stem cell medium in the absence of a feeder layer; and

(b) subculturing the first culture until a second stable culture with morphological features and growth parameters characteristic of an embryonic stem cell culture is established.

The examiner relies on the following references:

| | | |
|---|---|---|
| Wheeler | 5,523,226 | Jun. 4, 1996 |

Bazer et al. (Bazer), "Fertilization, Cleavage and Implantation," in Reproduction in Farm Animals, pp. 210-228 (1987)

Nichols et al. (Nichols), "Establishment of germ-line-competent embryonic stem (ES) cells using differentiation inhibiting activity," Development, Vol. 110, pp. 1341-1348 (1990)

Piedrahita et al. (Piedrahita), "On the Isolation of Embryonic Stem Cells: Comparative Behavior of Murine, Porcine and Ovine Embryos," Theriogenology, Vol. 34, No. 5, pp. 879-901 (1990)

Cruz et al. (Cruz), "Origin of Embryonic and Extraembryonic Cell Lineages in Mammalian Embryos," Current Communications In Cell & Molecular Biology, pp. 147-204 (1991)

Clark et al. (Clark), "Germ line manipulation: applications in agriculture and biotechnology," in Transgenic Animals, Grosveld et al. (eds.), Academic Press, New York, pp. 248-270 (1992)

Wurst et al. (Wurst), "Production of targeted embryonic stem cell clones," in Gene Targeting: A Practical Approach, A.L. Joyner (ed.), pp. 33-61 (1993)

Claims 15-20 stand rejected for obviousness-type double patenting over claims 1 and 2 of U.S. Patent 5,523,226.

Claims 1-6, 9-12, and 15-20 stand provisionally rejected for obviousness-type double patenting over claims 14-16 and 48-50 of application 08/473,030.

Claims 1-6, 9-12, and 15-20 also stand rejected under 35 U.S.C. § 112, first paragraph, as not supported by an enabling disclosure.

We affirm the rejections for double patenting and affirm-in-part and reverse-in-part the rejection for nonenablement.

Background

Appellant's specification discloses a method for isolating embryonic stem cells (ES-cells) from ungulates. See, e.g., pages 13-14. Ungulates include swine, cattle, sheep, and goats. Id., page 11. The embryonic stem cells can be genetically manipulated in culture and used to make transgenic animals via intermediate chimeric animals. See id., page 3.

"A chimeric organism is one that is a mixture of cells which differ in their genetic complements. When transformed ES-cells are used to make chimeric embryos, some of these cells may be incorporated into the gonads of the chimera and participate in the formation of sperm and ova. Incorporation of the transgene into a gamete permits germ line transmission. Consequently, some of the descendants produced by chimeric individuals will be transgenic." Id., page 4.

"Chimeric and transgenic animals are useful as models for diseases for the testing of pharmacological agents prior to clinical trials or the testing of therapeutic modalities. Another advantage is that more desirable qualities in farm animals may be produced by introducing transgenes with suitable expression products to improve qualities. These desirable qualities include increased efficiency in feed utilization, improved meat quality, increased pest and disease resistance, and increased fertility." Id., page 8.

## Discussion

### 1. Obviousness-type double patenting

The examiner rejected claims 15-20 for obviousness-type double patenting over claims 1 and 2 of Appellant's Patent 5,523,226, and provisionally rejected all of the claims on the same basis over the claims of Appellant's copending application 08/473,030. Appellant has not disputed the merits of these rejections and has agreed to file a terminal disclaimer to overcome them. See Paper No. 21 (filed Nov. 9, 1998), page 2. Since Appellant has not argued that the rejections are improper, we affirm them.

### 2. Enablement

The examiner rejected all of the claims as being broader than the enabling scope of the disclosure, on the basis that "the specification, while being enabling for swine, does not reasonably provide enablement for all ungulates." Examiner's Answer, page 4. In support of his position, the examiner cited several prior art references to show that mammalian species differ in their

embryonic development (see the Examiner's Answer, page 5). He also cited the specification as acknowledging the unpredictability in the art, in that it noted that "the established method for producing mouse embryonic stem cells can not [sic] be applied to other species." Examiner's Answer, pages 4-5.

The examiner acknowledged the declaration filed under 37 CFR § 1.132 by inventor Matthew B. Wheeler (attachment to Paper No. 16, filed Sept. 16, 1997), which allegedly showed "that the claimed methods have been used to produce sheep ES cells." Examiner's Answer, page 6. However, he concluded that the declaration did not overcome the rejection because

> the ES-like cells disclosed in the declaration do not meet an important art-accepted criterion of an ES cell, the ability to be incorporated into all cell types of an organism, particularly the germ line. . . . Appellant has demonstrated that the disclosed sheep ES-like cells have an appearance similar to swine ES cells, but not that they can be used to generate chimeric sheep and contribute fully functional gametes. . . . Hence those skilled in the art would not accept the ES-like cells described in the declaration as "true" ES cells based solely on their appearance, particularly since true sheep ES cells have not been produced previously and so there is no standard for comparison. In conclusion, there is no convincing evidence on the record that the disclosed methods will yield "true" ES cells of any species other than swine.

Id., pages 6-7. The examiner noted that "[t]he ability of the disclosed swine ES cells to contribute to the germ line was demonstrated in a declaration filed in the parent application, now patent no. 5,523,226." Id., page 7.

According to Appellant, claims 1-6 and 9-12 stand or fall together and claims 15-20 stand or fall together. Appeal Brief, page 3. Therefore, we will consider claims 1 and 15 as representative of the rejected claims.

A. Claims 1-6 and 9-12

Claim 1 is directed to a method of making a chimeric ungulate by introducing a cultured ungulate embryonic stem cell into a recipient embryo (of the same species as the ES-cell but differing genetically), to form a chimeric ungulate embryo, and "placing the chimeric ungulate embryo in an environment suitable for the completion of development to form a chimeric ungulate." The claim does not include any limitations on how the ungulate ES-cell used to make the chimeric animal is derived.

Appellant argues that the examiner did not give appropriate weight to the Wheeler declaration "that attests that sheep ES cells were prepared following the protocols of the present specification." Appeal Brief, page 5. Appellant argues that "[a]lthough it is true that there are some differences in embryonic development among ungulates, these differences are not shown by the Examiner to affect response of the different ungulate species to the methods of the present invention for producing chimeras." Id. (emphasis added).

We agree that the examiner has not shown that the claims directed to a method of making chimeric animals are not enabled. We note first that the claimed method does not require ungulate ES cells prepared by any particular method; thus the claimed method could be practiced using ES cells isolated from ungulate embryos using any appropriate method. We also note that, according to the specification, the ES cells used to make chimeric animals do not need to be totipotent. See page 11: "A method for making a chimeric ungulate to be

used in the invention includes introducing an ungulate embryonic stem (ES) cell that has a first genetic complement into a host embryo of the same species as the embryonic stem cell. A suitable embryonic stem cell is pluripotent, but a preferred cell is totipotent" (emphasis added).

Chimeric animals produced using pluripotent ES cells would not be expected to produce transgenic offspring ("[G]erm line transmission is required to produce transgenic animals, by definition," Reply Brief, page 5) but the specification discloses (page 12) that "there are uses for the chimeric ungulates even if they do not produce transgenic animals." For example, the specification discloses that chimeric animals can be made that express an exogenous gene (e.g., one encoding a human protein) "to provide a protein in recoverable form from the chimeric ungulate." Page 12, line 17 to page 13, line 7.

The examiner argues that "[i]t is well settled that more than one working example may be required to enable a broad genus, particularly in an unpredictable art." Examiner's Answer, page 4. We disagree. Working examples are a factor in determining whether undue experimentation would be required to practice the full scope of the claims, but even in an unpredictable art, there is no per se requirement for even one working example. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) ("Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations."). It may well be that, in some arts, the level of unpredictability will be so high that it is

practically impossible to enable a broad genus without one or more working examples. But in theory, at least, adequate enabling guidance could be provided via the other Wands factors, and therefore all relevant factors must be taken into account.

The examiner has provided numerous citations to the prior art to demonstrate the unpredictability of the field of embryonic stem cell research. See the Examiner's Answer, pages 5 and 6. However, the unpredictability appears largely to involve whether isolated ES-like cells will turn out to be "true," i.e., totipotent, ES cells. See, e.g., the Examiner's Answer, page 5 ("Furthermore, those skilled in the art recognize that not all 'ES-like' cells are 'true' ES cells, i.e. totipotent cells capable of contributing to the germ line of chimeric animals."). This is also the examiner's basis for giving little weight to the Wheeler declaration:

> Appellant has argued that the claimed methods have been used to produce sheep ES cells, citing the Wheeler declaration (paper 16). This argument is not persuasive because the ES-like cells disclosed in the declaration do not meet an important art-accepted criterion of an ES cell, the ability to be incorporated into all cell types of an organism, particularly the germ line. . . . In conclusion, there is no convincing evidence on the record that the disclosed methods will yield "true" ES cells of any species other than swine.

Examiner's Answer, pages 6-7.

Appellant naturally disputes this conclusion, but even if the examiner is correct, the unpredictability he relies on does not apply to the instant claims. Claims 1-6 and 9-12 are directed to a method of making a chimeric animal. The claimed method does not require totipotent ES cells, as made clear by the

specification. See the quoted passage from page 11, above. See also the Reply Brief, pages 5-6: "[G]erm line transmission is required to produce transgenic animals, by definition. However, no scientific or legal basis exists to require this for chimeric animals, because these are by definition, mixtures of genetically different cells, not necessarily in the germ line. It is, of course, preferred to have germ line chimeras to produce transgenic animals, but the claims are not to transgenic animals" (emphasis in original).

The examiner has not shown that undue experimentation would have been required to use pluripotent ungulate ES cells, made using the methods disclosed in the specification or methods known in the art, to produce a chimeric animal via the claimed method. Thus, the examiner has not shown that the specification does not enable the claimed method of making a chimeric animal. The rejection of claims 1-6 and 9-12 is reversed.

B. Claims 15-20

Claim 15 is directed to a method of isolating an ungulate embryonic stem cell culture, comprising "preparing a first culture by culturing dissociated cells from an ungulate embryo in conditioned stem cell medium in the absence of a feeder layer," and subculturing until a culture having the characteristics of an ES-cell culture is attained. The examiner concluded that practicing the full scope of the claimed method would have required undue experimentation, because

> the claims are broad, encompassing many divergent taxonomic groups. The state of the prior art is that others had incorrectly asserted that they had done what Appellant now claims, resulting in the skilled artisan setting a high standard of proof (demonstration of

> germ line transmission) before accepting that a cell line is an "ES cell line." This standard has been met only for swine; there are no other working examples. The art is unpredictable. It appears that the quantity of experimentation required to make and use the claimed invention for species other than swine would be high.

Examiner's Answer, page 8.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

In this case, the examiner has provided a reasonable explanation, supported by evidence, of why the full scope of claim 15 is not enabled by the guidance provided in the specification. The examiner has cited numerous prior art references supporting his position that isolating embryonic stem cells is a highly unpredictable endeavor. See the Examiner's Answer, pages 5-7. The examiner cites Cruz and Bazer as "list[ing] some of the differences in early embryonic development" among ungulates and "provid[ing] an overview of differences among ungulate species," respectively. Examiner's Answer, page 5.

The examiner, however, does not explain how these differences would contribute to the experimentation required to practice the claimed method.

But the examiner goes on to cite other references and explain their relevance to enablement. He notes that "Piedrahita et al. observed that porcine and ovine embryos responded differently to the same treatments. Conditions which allowed production of porcine ES-like cell lines did not allow development of ovine ES-like cell lines (e.g. Table 1). Piedrahita et al. state, 'Ovine intact embryos and isolated ICM [inner cell mass] behaved differently than porcine embryos' (p. 888)." Examiner's Answer, page 5.

We agree that Piedrahita provides evidence that a protocol producing ES cells from one ungulate species (e.g., pigs) will not necessarily produce ES cells when applied to a different ungulate species (e.g., sheep). Piedrahita stated that the purpose of the disclosed experiments was "to compare the behavior of murine, ovine, and porcine embryos under conditions known to lead to the production of murine embryonic stem cells." Piedrahita, page 880. They found "marked differences in the efficiency of isolation and the characteristics of embryo-derived cell lines from murine, porcine, and ovine embryos." Id. Piedrahita also stated that they did not know the basis for the differing behavior of the porcine and ovine cells. See page 897: "Whether the difficulties encountered in the isolation of ES cells from porcine and ovine embryos were due to inherent species differences, which make such isolation feasible, or whether the difficulties were due to inappropriate culture conditions or source of

embryonic material (e.g., embryos that were too young or too old) remains to be determined."

The Nichols, Wurst, and Clark references cited by the examiner also provide evidence of nonenablement. Nichols teaches that, as of 1990, "[t]he parameters governing the successful derivation and propagation of pluripotential ES cells [were] poorly characterised." Page 1341. Nichols reports a procedure for isolating ES cells by culturing in the absence of feeder cells, as in the instant claims. See the abstract. However, the resulting ES cells showed a high degree of chromosomal abnormality. See page 1347: "Only one of the fifteen lines established had an entirely normal karyotype. . . . The others showed varying degrees of chromosomal abnormality. Published data from one laboratory . . . indicates [sic] that the majority (27 out of 35) of cell lines derived on feeders are initially euploid [i.e., chromosomally normal]." Importantly, Nichols could only guess at the reason for the increased chromosomal defects: "These data suggest there may be some advantages to the use of feeders. However, this success could also be due to the mouse strains used and/or to the particular culture environment. Other workers have reported that not all ES lines differentiate normally and relatively few exhibit high levels of germ-line transmission." Nichols therefore evidences the unpredictability involved in applying a method of isolating ES cells not only to different species, but to different strains within the same species, e.g., different strains of mice.

Although Nichols was published three years before the effective filing date of the instant application, Wurst provides evidence that the unpredictability evidenced by Nichols still plagued the field in 1993. See page 41:

> In our experience each ES cell line has different requirements for continued growth in an undifferentiated state and maintenance of their ability to contribute to the germline. We have had most experience with D3 and R1 cells and the following protocol is recommended for these cell lines. For other cell lines, you should consult the laboratory where the cell line was generated. The parameters that need to be considered are:
>
> - growth media
> - length of growth between passages
> - number of cells to be plated at each passage
> - extent of trypsinization
> - % $CO_2$ in the incubator
> - feeder layer type

Thus, Wurst provides further evidence that protocols developed for a particular cell type or line would not have been expected to be applicable to other cells, even other cell lines derived from the same species. Although Wurst's discussion is specific to maintaining ES cell lines in an undifferentiated state, it is reasonable to conclude that the same concerns would apply to isolating an ES cell line in the first place, since the record shows that numerous researchers failed in their attempts to isolate ES cells. See, e.g., the discussion of the prior art on pages 5-7 of the specification.

Clark, published in 1992, reports that "[t]he isolation of ES cells from domestic livestock has not yet been conclusively demonstrated. Isolation and culture of inner cell mass cells from sheep embryos has been accomplished but it

has proved difficult to establish undifferentiated cell lines from these." Page 250. Clark notes hopefully that "[r]ecently, however, Notarianni et al. (1990) have described the derivation of apparently pluripotent, embryonic cell lines from porcine and ovine blastocysts." Id. The instant specification, however, disputes the contribution of Notarianni to the state of the art. See page 5: "Notarianni et al. (1990) reported methods to produce transgenic pigs by use of pluripotent stem cells, but did not convincingly show that pluripotent embryonic stem cells were produced."

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" In re Wright, 999 F.2d at 1561, 27 USPQ2d at 1513. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Among the considerations that may be relevant are "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Id. at 737, 8 USPQ2d at 1404.

We agree with the examiner that most of the Wands factors weigh against enablement of the instant claims. The claims read on isolating ES cells from any

type of hoofed mammal (ungulate), and thus encompass ES cells from a variety of different species. The record shows that a great deal of experimentation is required to isolate each potential ES cell line from embryonic cells (see, e.g., Piedrahita, Nichols, and the instant specification, pages 69-74) and that each potential ES cell line must be validated by another labor-intensive process to determine whether it in fact has the capacity to differentiate into many different types of cells. See the specification, page 10, lines 13-31.

The record also shows that embryonic cells from different ungulate species, and even cells from different strains within the same species, respond differently to the same protocol intended to isolate or maintain ES cells. See Nichols and Wurst. The field of the invention is therefore characterized by a high degree of unpredictability and the need to empirically determine culture conditions and other experimental parameters for each ES cell line individually. Although those of skill in the art would possess a high degree of skill, as shown by the technical sophistication of the references in evidence, the state of the prior art would not have contributed to the scope of enablement since the prior art showed few, if any, successful examples of isolated ungulate ES cells.

The specification provides detailed guidance with respect to porcine ES cells, which are also exemplified, but little additional guidance and no working examples of ES cells from other ungulates. Essentially, the specification asserts that the same protocol used in pigs would be successful when applied to other ungulates, with the only necessary modification being the timing of harvesting

cells from the developing embryo. See, e.g., Table 2 on page 44. Those skilled in the art would reasonably doubt this assertion based on the evidence provided in the prior art cited by the examiner.

We therefore conclude that the examiner has carried his "initial burden of setting forth a reasonable explanation as to why [he] believes that the scope of protection provided by th[e] claim is not adequately enabled by the description of the invention provided in the specification of the application." In re Wright, 999 F.2d at 1561-62, 27 USPQ2d at 1513. The burden therefore "shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling." Id.

Appellant argues that there is no legal requirement for a working example and the specification provides adequate guidance with respect to both pigs and other ungulate species. See the Appeal Brief, pages 3-5 and 6-7. These arguments are adequately addressed above. To recap, although a working example is not required, its absence is one factor to be weighed in the Wands analysis, and our review of the record as a whole convinces us that the guidance provided by the specification is inadequate to enable those skilled in the art to practice the claimed invention throughout its scope without undue experimentation.

Appellant also argues that he has filed a declaration under 37 CFR § 1.132 showing that "sheep ES cells were prepared following the protocols of the present specification." Appeal Brief, page 5.

This argument is unpersuasive. Claim 15 is directed to a method of isolating ES cells by culturing "in the absence of feeder layers." The process described in the Wheeler declaration, by contrast, uses feeder layers. See paragraphs 6 and 7:

> 6. Embryonic stem cells were isolated from sheep blastocysts. . . . Hatched blastocysts were flushed from the uterus of donors. . . . Embryos were . . . cultured individually on mitomycin C-inactivated mouse embryonic fibroblasts (STO) monolayers. . . .
>
> 7. The inner cell mass (ICM) of the cultured sheep embryo was evident during the first 1-14 days of culture. After the ICM emerged, usually 7-9 days in culture, the whole embryonic cell colony was partially disaggregated . . . [and] re-seeded onto new mitomycin C-inactivated STO feeder layers. For all subsequent passages the cells were plated onto fresh feeder layers.

(emphasis added). Since the declaration does not show the applicability of the claimed method to other ungulates, it cannot be relied on as evidence that the specification is enabling for the claimed method. Whether other, disclosed but unclaimed, methods of making ungulate ES cells might be enabled is not an issue in this appeal.

Appellant also disputes the relevance of Piedrahita to the instant claims, arguing that "there is no evidence that ES cells were produced. There was no assertion that ovine embryos produced ES cells. . . . Applicant maintains that ES cells were not produced by Piedrahita et al., therefore, the examiner's concern 'that porcine and ovine embryos responded differently to the same treatments' . . . is not supported by Piedrahita." Appeal Brief, pages 5-6.

Appellant's argument is unpersuasive. Even assuming that Appellant is correct, and the porcine cells isolated by Piedrahita were not in fact ES cells, Piedrahita still discloses that "ES-like" cells were isolated from porcine embryos, while the same procedure did not result in even "ES-like" cells when applied to ovine embryos. Even assuming arguendo that Appellant is correct, therefore, the reference is still evidence that embryonic cells from different ungulates respond differently to the same treatment.

Finally, Appellant argues that, although there are differences between ungulate species, ungulates also share similarities that are not mentioned by the examiner. See the Appeal Brief, page 6:

> The Examiner points to "differences" among species reported by Cruz et al. and by Bazer et al., but selectively fails to mention similarities among ungulates described in these publications, e.g., "The pattern of development during cleavage is similar for all farm species studied" (see Table 8-2). Table 8-2 relates [to] cattle, horse, sheep and swine. Therefore, it is reasonable to expect the invention is suitable for all ungulates.

Appellant, however, fails to explain why the pattern of development during cleavage would have led those skilled in the art to expect the claimed method to be successful when applied to other ungulates. This argument is therefore not persuasive.

## Other Issues

### (A) Claims 15-20

We note that the examiner and Appellant devoted a lot of effort to the issue of whether enablement requires pluripotent or totipotent stem cells. The

examiner seems to take the position that only totipotent stem cells would be "true" embryonic stem cells sufficient to satisfy the requirements of claims 15-20. This position appears to be in error. The specification states that "[i]n the present invention, limitations of the art are overcome by the production of stable, pluripotent ungulate embryonic stem cell cultures." Page 10, lines 6-8 (emphasis added). Thus, it would appear that the specification defines embryonic stem cells to include cells that are pluripotent.

The specification also discloses that pluripotential embryonic stem cells are suitable for making chimeric animals (page 11, lines 18-23) and that chimeric animals are useful even if they do not produce transgenic offspring (page 12, lines 14-16). Therefore, it would not appear that totipotent embryonic stem cells are required to practice the claimed method. Although we disagree with this aspect of the examiner's reasoning, we agree with his ultimate conclusion that the claims are not fully enabled, as discussed in detail above.

(B) Claims 1-6 and 9-12

Claims 1-6 and 9-12 are directed to a method of making chimeric animals using ES cells. As noted above, these claims do not require that the ES cells used be isolated by any particular method, and the specification states that pluripotential ES cells can be used to make chimeric animals. We note that some of the prior art references in the record relate to methods of making chimeric ungulates using pluripotential ES cells. See, e.g., Evans et al. (WO 90/03432), titled "Derivation of pluripotential embryonic cell lines from domestic

animals." See also page 14: "[T]he fresh cells can be introduced to a host blastocyst [which] can then be introduced to the uterus of a pseudopregnant foster mother where it may develop into a chimaeric animal." See also Williams et al. (WO 90/01541).

In view of the discussion above, the examiner may wish to reassess the patentability of claims 1-6 and 9-12 over the prior art. We emphasize that we have not considered the detailed disclosures of the references noted above, and we intimate no position on the ultimate question of whether the references anticipate or render obvious the claimed method. The examiner is in a better position to compare the claim limitations with the prior art disclosures.

Summary

We affirm the rejections for obviousness-type double patenting. We also affirm the rejection of claims 15-20 for nonenablement because the examiner has made out a prima facie case of nonenablement, which has not been rebutted. However, we reverse the rejection of claims 1-6 and 9-12 for nonenablement because the examiner has not shown that undue experimentation would have been required to practice the claimed method of making a chimeric ungulate.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)

AFFIRMED

WILLIAM F. SMITH )
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)
)
DONALD E. ADAMS ) BOARD OF PATENT
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